UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GARY S. GRUBB

Appeal 2007-1072
Application 09/872,250
Technology Center 1600

ON BRIEF

Before SCHEINER, ADAMS, and GREEN, *Administrative Patent Judges.*

GREEN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-11. Claim 1 is representative of the claims on appeal, and reads as follows:

1. An oral contraceptive starter kit comprising at least two cycle packs of oral contraceptives containing an estrogen and progestin, and having a penultimate and a last cycle pack, the effective dosage of steroid in the penultimate cycle pack being greater than the effective dosage of steroid in the last cycle pack, the last cycle pack providing no more than about 20 μg estrogen per dosage unit.

Claims 1-11 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Endrikat,[1] Hodgen[2] and Katzung.[3] We reverse.

DISCUSSION

Claim 1 is drawn to a kit, wherein at least two cycle packs are packaged together to be given to a patient, wherein one pack has an effective dosage of steroid that is greater than the effective dosage of steroid in the second pack, wherein the cycle pack having the lower effective dosage of steroid has no more than about 20 μg estrogen per dosage unit.

Endrikat is relied upon by the Examiner for teaching that oral contraceptives having 30 μg of ethinylestradiol have less breakthrough bleeding in the first three cycles than those having 20 μg of ethinylestradiol (Answer 3). The examiner also cites Endrikat for its teaching that the pattern of breakthrough bleeding in the first month may be due to the fact that the adaptation of the endometrium to the exogenous hormones takes some time. *Id.*

Hodgen is cited for teaching "a method of reducing breakthrough bleeding in the menstrual cycles except for the first cycle employing ultra-low dose of ethinylestradiol," wherein the dose is 3-35 μg. *Id.*

Katzung is relied upon for teaching the various claimed progestins. *Id.* at 4. The examiner acknowledges that the "primary references do not

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[1] Endrikat et al. (Endrikat), *A Twelve-Month Comparative Clinical Investigation of Two Low-Dose Oral Contraceptives Containing 20 μg Ethinylestradiol/75 μg Gestodene and 30 μg Ethinylestradiol/75 μg Gestodene, with Respect to efficacy, Cycle Control, and Tolerance*, Contraception, Vol. 55, pp. 131-137 (1997).
[2] Hodgen, U.S. Pat. No. 5,552,394, issued September 3, 1996.
[3] Katzung, *Basic & Clinical Pharmacology*, p. 120 (6th Ed. 1995).

expressly teach the combination of the oral contraceptives packs together in a kit."

The Examiner concludes:

> One of ordinary skill in the art would have been motivated to combine the oral contraceptive[ ] packs of 30mcg and 20mcg of Ethinylestradiol together in a kit. Hodgen's method of reducing breakthrough bleeding has one drawback, which cannot reduce the breakthrough bleeding in the first cycle. Possessing the teachings of Endrikat, one of ordinary skill in the art would reasonably expect to employ a regimen comprising a dose of 30mcg of ethinylestradiol in the first cycle in the Hodgen's method in order to let the endometrium adapt to the exogenous hormones as well as reduce the breakthrough bleeding in the first cycle and thereby improving Hodgen's method.

Id. at 4.

Appellant argues that both Endrikat and Hodgen administer oral contraceptives from one month to the next having "an identical content as the oral contraceptive administered in the first month" (Br. 10).[4] Appellant asserts that it is only through the use of impermissible hindsight that one would arrive at the claimed invention—a kit combining a high dose oral contraceptive pack combined with a low dose oral contraceptive pack. *Id.* at 15. We agree, and the rejection is reversed.

"[T]he Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. '[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that

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[4] All references to the Brief are to the Revised Brief dated May 12, 2006.

knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (citation omitted). An adequate showing of motivation to combine requires "evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" *Ecolochem, Inc. v. Southern Calif. Edison Co.*, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1076 (Fed. Cir. 2000). "[T]he best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references." *Id.*, 227 F.3d at 1371, 56 USPQ2d at 1073.

Endrikat is drawn to a clinical study "to compare contraceptive reliability, cycle control, and tolerance of an oral contraceptive containing 20 μg ethinylestradiol (EE2) and 75 μg gestodene (GSD), with a reference preparation containing a similar dose of gestodene but in combination with 30 μg ethinylestradiol." *Id.*, abstract. The reference teaches that of the subjects taking the higher dose of ethinylestradiol, 13.8% reported spotting in the first cycle, while 22.6% of the subjects taking the lower dose reported spotting in the first cycle. *Id.* at 133, col. 2. With respect to breakthrough bleeding, Endrikat notes that highest incidence was reported by 2.4% of the subjects in the third 20 μg EE2 cycle and by 2.3% in the first 30 μg EE2 cycle. *Id.*

Endrikat notes that "the data . . .showed slightly less favorable bleeding patterns for the 20 μg EE2 preparation," with the occurrence of

spotting as well as normal/excessive breakthrough bleeding decreasing during use, and that the highest incidence of any intermenstrual bleeding occurred during the first cycle. *Id.* at 136, col. 1. Endrikat concludes "the results of this comparative study show that the reduction of EE2 content from 30 μg to 20 μg neither comprises contraceptive reliability nor leads to clinically unacceptable cycle control." *Id.* at 136, col. 2.

Hodgen relates to a method of oral contraception in which the incidence of breakthrough bleeding is reduced after the first cycle. Hodgen teaches a oral contraceptive containing "a combined dosage form of estrogen and progestin monophasically for 23 to 25 consecutive days of a 28 day cycle, preferably 24 days of the cycle, in which the daily amounts of estrogen and progestin are equivalent to about 5-35 mcg of ethinyl estradiol and about 0.025 to 10 mg or norethindrome acetate, respectively, and in which the weight ratio of estrogen to progesterone is at least 1:45 calculated as ethinyl estradiol to norethindrone acetate." *Id.* at col. 3, ll. 52-61. Thus, Hodgen solves the problem of breakthrough bleeding in months subsequent to the first month through the addition of norethindrome acetate to the oral contraceptive preparation.

Endrikat is drawn to a clinical study comparing oral contraceptives containing 20 μg of EE2 and 30 μg of EE2, with spotting and breakthrough bleeding occurring with both preparations, although admittedly with a slightly lower incidence with the higher EE2 containing preparation. Hodgen is drawn to reduction of breakthrough bleeding after the first cycle of use, wherein norethindrone acetate is included in a preparation containing a combination of estrogen and progestin. Thus, as noted by Appellant, both

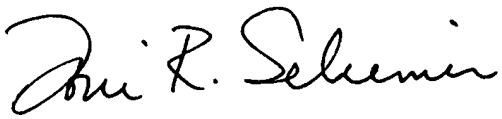
references teach the use of a preparation containing an identical content of the oral contraceptive administered in the first month and each subsequent month.

We can find no motivation to arrive at the claimed kit containing two cycle packs of oral contraceptives, one pack containing a lower effective dosage of steroid than the second pack, either in the prior art or the general knowledge in the as art set forth in the record by the examiner, except Appellant's own disclosure. Thus, as the Examiner has not met the burden of *prima facie* case of obviousness, we are compelled to reverse the rejection.

SUMMARY

Because the examiner has failed to set forth a *prima facie* case of obviousness, the rejection is reversed.

REVERSED



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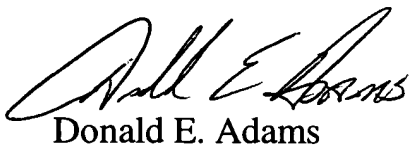
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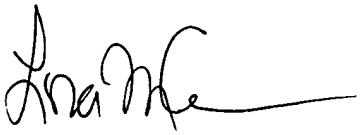
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